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18N1/1129

DANN, DOFFMAN, HERRELL AND SKILLMAN  
1601 MARKET STREET  
SUITE 720  
PHILADELPHIA, PA 19103-2307

**NOTICE OF ALLOWANCE  
AND ISSUE FEE DUE**

- ☐ Note attached communication from the Examiner  
☐ This notice is issued in view of applicant's communication filed \_\_\_\_\_

| SERIES CODE/SERIAL NO. | FILING DATE     | TOTAL CLAIMS | EXAMINER AND GROUP ART UNIT | DATE MAILED   |
|------------------------|-----------------|--------------|-----------------------------|---------------|
| 08/211,800             | 06/22/94        | 016          | BEES, D                     | 1997 11/29/95 |
| First Named Applicant  | EKINS, ROGER P. |              |                             |               |

TITLE OF INVENTION  
BINDING ASSAY EMPLOYING LABELLED REAGENT

| ATTY'S DOCKET NO. | CLASS-SUBCLASS | BATCH NO. | APPLN. TYPE | SMALL ENTITY | FEE DUE   | DATE DUE |
|-------------------|----------------|-----------|-------------|--------------|-----------|----------|
| 1 6174            | 435-006,000    | BSO       | UTILITY     | NO           | \$1250.00 | 02/29/96 |

**THE APPLICATION IDENTIFIES ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED.**

**THE ISSUE FEE MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED.**

**HOW TO RESPOND TO THIS NOTICE:**

- I. Review the SMALL ENTITY Status shown above.  
If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:
  - A. If the status is changed, pay twice the amount of the FEE DUE shown above and notify the patent and Trademark Office of the change in status, or
  - B. If the Status is the same, pay the FEE DUE shown above.
- II. Part B of this notice should be completed and returned to the Patent and Trademark Office (PTO) with your ISSUE FEE. Even if the ISSUE FEE has already been paid by charge to deposit account, Part B should be completed and returned. If you are charging the ISSUE FEE to your deposit account, Part C of this notice should also be completed and returned.
- III. All communications regarding this application must give series code (or filing date), serial number and batch number. Please direct all communication prior to issuance to Box ISSUE FEE unless advised to contrary.

If the SMALL ENTITY is shown as NO:

- A. Pay FEE DUE shown above, or
- B. File verified statement of Small Entity Status before, or with, pay of 1/2 the FEE DUE shown above.

**IMPORTANT REMINDER: Patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.**

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Washington, D.C. 20231

| ORIGINAL NUMBER | FILING DATE | FIRST NAMED APPLICANT | ATTORNEY DOCKET NO. |
|-----------------|-------------|-----------------------|---------------------|
| 08/211,000      | 06/22/94    | ERINS R               | 6174                |

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REES, D EXAMINER

| ART UNIT | PAPER NUMBER |
|----------|--------------|
| 1807     | 14/E         |

11/29/95

DATE MAILED:

NOTICE OF ALLOWABILITY

PART I.

- 11-8-95  
9-22-95
- ☒ This communication is responsive to 9-22-95
  - ☐ All the claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice Of Allowance And Issue Fee Due or other appropriate communication will be sent in due course.
  - ☒ The allowed claims are 32-47, renumbered as 1-16
  - ☐ The drawings filed on \_\_\_\_\_ are acceptable.
  - ☒ Acknowledgment is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☒ been received. ☐ not been received. ☐ been filed in parent application Serial No. 05-211800 filed on 6/22/94  
PCT/GB92/01892 10/15/92
  - ☐ Note the attached Examiner's Amendment.
  - ☐ Note the attached Examiner Interview Summary Record, PTOL-413.
  - ☐ Note the attached Examiner's Statement of Reasons for Allowance.
  - ☐ Note the attached NOTICE OF REFERENCES CITED, PTO-892.
  - ☒ Note the attached INFORMATION DISCLOSURE CITATION, PTO-1449.

PART II.

A SHORTENED STATUTORY PERIOD FOR RESPONSE to comply with the requirements noted below is set to EXPIRE THREE MONTHS FROM THE "DATE MAILED" indicated on this form. Failure to timely comply will result in the ABANDONMENT of this application. Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

- ☐ Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL APPLICATION, PTO-152, which discloses that the oath or declaration is deficient. A SUBSTITUTE OATH OR DECLARATION IS REQUIRED.
- ☒ APPLICANT MUST MAKE THE DRAWING CHANGES INDICATED BELOW IN THE MANNER SET FORTH ON THE REVERSE SIDE OF THIS PAPER.
  - ☒ Drawing informalities are indicated on the NOTICE RE PATENT DRAWINGS, PTO-948, attached hereto or to Paper No. 9. CORRECTION IS REQUIRED.
  - ☐ The proposed drawing correction filed on \_\_\_\_\_ has been approved by the examiner. CORRECTION IS REQUIRED.
  - ☐ Approved drawing corrections are described by the examiner in the attached EXAMINER'S AMENDMENT. CORRECTION IS REQUIRED.
  - ☐ Formal drawings are now REQUIRED.

Any response to this letter should include in the upper right hand corner, the following information from the NOTICE OF ALLOWANCE AND ISSUE FEE DUE: ISSUE BATCH NUMBER, DATE OF THE NOTICE OF ALLOWANCE, AND SERIAL NUMBER.

Attachments:

- ☒ Examiner's Amendment
- ☒ Examiner Interview Summary Record, PTOL-413
- ☐ Reasons for Allowance
- ☐ Notice of References Cited, PTO-892
- ☒ Information Disclosure Citation, PTO-1449

- ☐ Notice of Informal Application, PTO-152
- ☐ Notice re Patent Drawings, PTO-948
- ☐ Listing of Bonded Draftsmen
- ☐ Other

**Part III EXAMINER'S AMENDMENT**

1. An Examiner's Amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 C.F.R. § 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the Issue Fee.

The application has been amended as follows:

In claims 33, 35-37, 40-44, at line 1, delete "32" and substitute --1--.

In claim 38, at line 1, delete "37" and substitute --6--.

In claim 39, at line 1, delete "38" and substitute --7--.

In claim 47 delete "46" and substitute --16--.

2. The following is an Examiner's Statement of Reasons for Allowance:

The claims are drawn to an assay process and kit which uses binding agents specific for one or more analytes which is immobilized at high density as one or more microspots in combination with a developing binding material labelled with microspheres. The assay taught can achieve sensitivities over other known assays, for example in TSH assays, of over 50-500 times better than provided by currently available assay methods. The closest prior art of record is Ekins (USPAT 5171695) who teaches the use of analytes bound to microspots but does not

specifically teach the immobilization of analytes at high density on said microspots (as taught in the specification of the present application, at least 1000 molecules/ $\mu\text{m}^2$ ). Therefore the present assay of the instant invention provides an improved signal to noise ratio when signal from a labelled molecule is measured and the high density of the capture binding agent helps reduce the nonspecific binding of a developing binding material. Although the use of fluorescent microspheres was known in the art at the time of the invention, the use of microspheres in assays designed to detect small amounts of analytes was not taught, nor were methods provided to overcome background or enhance sensitivity (the prior art in fact taught high backgrounds when fluorescent microspheres were used). It is the combination of microspheres and the immobilization of analytes at high density in the method that distinguishes the present invention over that of Ekins (USPAT 5171695). The art does not teach nor fairly suggest this combination which provides the unexpected result of allowing for a surprisingly sensitive assay for the detection of small amounts of analytes.

Any comments considered necessary by applicant must be submitted no later than the payment of the Issue Fee and, to avoid processing delays, should preferably accompany the Issue Fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Serial Number: 08211800  
Art Unit: 1807


-4-

3. Papers related to this application may be submitted to Group 1800 by facsimile transmission via the P.T.O. Fax Center located in Crystal Mall 1. The CM1 Fax Center number is (703) 305-4227. Please note that the faxing of such papers must conform with the notice to Comply published in the Official Gazette, 1096 OG 30 (Nov 15, 1989).

An inquiry regarding this communication should be directed to examiner Dianne Rees, Ph.D., whose telephone number is (703) 308-6565. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703) 308-1156.

Calls of a general nature may be directed to the Group receptionist who may be reached at (703) 308-0196.

Dianne Rees  
Nov 9, 1995

  
W. GARY JONES  
SUPERVISORY PATENT EXAMINER  
GROUP 1800  
11/15/95